Section 3 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: _____

1. Date of Submission: Mar. 15, 2013

SEP 16 2013

2. Sponsor Identification

Beijing Jinhengwei Technology Development Co.,Ltd.
East side on 2nd floor of south building,No.631 xingong village,
Nanyuan area, Fengtai District, Beijing, China 100069

Establishment Registration Number: Not yet registered

Contact Person: Mr. Ligang Mao
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3. Submission Correspondent

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4. Proposed Device Identification

Proposed Device Name: Electrosurgical Generator
Proposed Device Model: HV-400, HV-300A
Device Common Name: Electrosurgical Unit and Accessories

Regulatory Information:
Classification Name:Electrosurgical Unit and Accessories;
Classification: II;
Product Code: GEI;
Regulation Number: 21 CFR 878.4400;
Review Panel: General& Plastic Surgery;

Intended Use Statement:

The Electrosurgical Generator (HV-300A, HV-400) is a non-sterile, reusable multi-purpose electrosurgical generator that is designed to perform monopolar and bipolar functions in the operating arena.

5. Predicate Device Identification

510(k) Number: K072041
Predicate Device Name: Bovie IDS-400
Manufacturer: Bovie Medical

510(k) Number: K944602
Predicate Device Name: Force FX
Manufacturer: Valleylab Inc.

6. Device Description

The proposed device (HV-400 and HV-300A) is an electrosurgical generator with, monopolar and bipolar, high frequency current isolation outputs.

The proposed device is independent equipment, which include generator and accessories. The main components are front panel (power switch, touchable screen, operation key, indicator, connector for accessories), back panel (volume controller, foot switch interface, power cable outlet and fuse) and inner component (display panel, main board, control board, speaker etc.). The accessories include power cable,

cable and foot switch).

The two models of proposed device share the same appearance, function, accessories, the only difference is the output parameter

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

IEC 60601-1:2005 Medical electrical equipment Part 1: General requirements for basic safety and essential performance.

IEC 60601-1-2:2007 Medical electrical equipment Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic compatibility - requirements and tests

IEC 60601-2-2:2009 Medical electrical equipment Part 2-2: Particular requirements for safety of high frequency surgical equipment.

8. Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate device with respect to intended use, technological characteristics and principles of operation, etc.

Table 3-1 Comparison of Technology Characteristics

Item	Proposed Device(s)	Predicate Device (K072041)	Predicate Device (K944602)
Product Code	GEI	Same	Same
Regulation Number	878.4400	Same	Same
Intended Use	The Electrosurgical Generator (HV-300A, HV-400) is a non-sterile, reusable multi-purpose electrosurgical generator that is designed to perform monopolar and bipolar functions in the operating arena.	Same	Similar
Type	HF energy	Same	Same
Output waveform	Monopolar and bipolar	Same	Same

Operation system	Touchable TFT screen and foot switch	Same	Same
Working voltage	110-220V AC±10%	Same	Same
Safety	IEC 60601-1	Same	Same
EMC	IEC 60601-1-2	Same	Same
Performance	IEC 60601-2-2	Same	Same
Features	LCD touchable screen, foot switch	Same	Same

The proposed device(s), Electrosurgical Generator (HV-300A, HV-400), are determined to be Substantially Equivalent (SE) to the predicate device(s), Bovie IDS-400 and Force FX, in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Beijing Jinhengwei Technology Development Corporation, Ltd.
Mr. Ligang Mao
General Manager
East side on 2nd Floor of south building, No.631 xingong village
Nanyuan area, Fengtai District, Beijing, China 100069

September 16, 2013

Re: K130760
Trade/Device Name: Electrosurgical Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 23, 2013
Received: August 1, 2013

Dear Mr. Mao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Neil R Ogden
2013.09.26 14:29:58 -04'00'

for Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K130760

Section II Indications for Use

510(k) Number:
Device Name:

Indications for Use:

The proposed device is intended for use is:

The Electrosurgical Generator (HV-300A, HV-400) is a non-sterile, reusable multi-purpose electrosurgical generator that is designed to perform monopolar and bipolar functions in the operating arena.

☒ PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐ OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -A

(Division Sign-off) for MXM
Division of Surgical Devices
510(k) Number ___K130760____